

## **REMARKS**

Applicant's counsel thanks the Examiner for the careful consideration given the application and for the courteous telephone interview conducted on February 3, 2009 in which the participants were Applicant's undersigned counsel, Examiner Aradhana Sasan and SPE Michael Woodward. During the telephone interview, it was agreed that claim 1 would be amended substantially as it has now been amended. The substance of the interview is as follows.

Applicant's counsel pointed out that pelletizing of the prior art particles subjected those particles to very harsh conditions, which frequently caused the prior art particles to leak, wherein humidity could attack the choline chloride at the core of the particle. One of the key features of applicant's invention was the discovery that a second, outer layer of carnauba wax could effectively protect the particle from damage during the harsh pelletizing process. As discussed during the interview, applicant has now amended claim 1 to add the limitation that the composition is a pellet comprising particles compressed together via pelletization. The addition of this limitation does two things: it focuses claim 1 on a key feature of applicant's invention, and clearly defines over the prior art. The prior art in the Examiner's Office action is Riga, US 6,174,890. By adding the pellet limitations to claim 1, applicant has clearly defined over Riga; Riga teaches, at column 10, lines 3-8, that his composition is introduced in hard gelatin capsules, and may also be encased in soft gelatin capsules; Riga does not teach pelletization.

Next, during the interview, it was pointed out that the choline chloride in the core of the particle is very hygroscopic and must be protected from moisture. That is why the inner layer of applicant's coating is a hydrophobic substance such as vegetable oil. The Riga reference relied upon in the Office action is totally dissimilar. First, Riga is not protecting choline chloride, rather, Riga is protecting a completely different material, nicotinic acid. Second, Riga is, as understood, using as his first layer a layer of ethyl cellulose. Ethyl cellulose has a high affinity for water. When placed in a humid environment, ethyl cellulose swells and releases water to the underlying materials, especially when the latter are highly hygroscopic such as choline chloride. Thus, a person of ordinary skill in the art, faced with the problem of trying to protect a choline chloride particle coated with a hydrophobic substance from the harsh conditions of pelletization, would certainly not look to Riga for any assistance, since Riga does not have a choline chloride core, it does not have a first layer of hydrophobic material (it has ethyl cellulose, which has a high affinity for water) and he does not pelletize his particles.

It has been pointed out that Riga adds a second layer (of carnauba wax). However, applicant's counsel argues that Riga is adding his outer layer of carnauba wax (a hydrophobic substance) because his first layer (ethyl cellulose) doesn't provide hydrophobicity; to get hydrophobicity, he has to add an outer layer of carnauba wax. Applicant argues that applicant's first layer already provides hydrophobicity (vegetable oil). There is no need for a second layer (carnauba wax) to provide hydrophobicity, so there is no point to add carnauba wax as an overcoat on top of our vegetable oil; applicant's particle already has moisture protection. Thus, Riga's teaching of adding an outer hydrophobic layer is of no value to applicant, since applicant does not need an outer hydrophobic layer, since applicant's inner layer is already hydrophobic. As mentioned during the interview, applicant has now emphasized this distinction over the prior art by adding a new limitation to claim 1, that being "said inner layer providing effective protection of the choline chloride from moisture". Certainly this defines over Riga, since Riga's inner layer of ethyl cellulose does not provide effective protection from moisture, and in particular does not provide protection of choline chloride from moisture, since Riga does not have choline chloride.

Next, during the interview, it was pointed out that Riga is teaching pharmaceuticals for use in humans; Riga doesn't have anything to do with ruminants or polygastric animals. Applicant's counsel has now added additional limitations to the claims to more positively limit claim 1 to ruminants and positively define over the human pharmaceuticals of Riga. Specifically, the following wording has now been presented in claim 1 "each particle comprising a core which contains choline chloride and a protective coating surrounding the core which provides effective protection of the choline chloride from ruminal activity while allowing effective release of the choline chloride into the post-rumen portion of the digestive tract of the ruminant". By limiting claim 1 to ruminants, this further defines over the Riga reference (which is directed to non-ruminant, monogastric, humans).

In summary, it was pointed out during the telephone interview that claim 1 has been limited in three ways to more clearly define over the Riga reference, these being: (a) the composition being a pellet comprising particles compressed together via pelletization, (b) the particles having an inner layer which provides effective protection of the choline chloride from moisture (Riga's inner layer is ethyl cellulose) and (c) positively reciting in claim 1 that the particle provides effective protection of the choline chloride from ruminal activity while allowing effective release of the choline chloride into the post-rumen portion of the digestive tract of the ruminant. Since

claim 1 has now been amended in all these ways, and now more positively recites the distinguishing features of the invention, it is clear that claim 1 as now presented is patentable over Riga. At the conclusion of the interview, SPE Woodward said that the arguments sounded good and seemed to be persuasive, but that he would have to see the Amendment and the arguments in writing and then he would make a final evaluation.

For all the reasons set forth above, it is clear that claim 1, as now limited and more positively stated, defines over the prior art and should be allowed. All the other claims are dependent claims and should be allowable due to their dependency.

It is believed that the claims as now amended and defined are in condition for allowance, which is respectfully requested. If the Examiner sees further issues, the Examiner is requested to contact applicant's counsel with a view to resolve the differences. If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-36500.

Respectfully submitted,  
PEARNE & GORDON LLP

By John P. Murtaugh  
John P. Murtaugh, Reg. No. 34226

1801 East 9<sup>th</sup> Street, Suite 1200  
Cleveland, Ohio 44114-3108  
Phone: (216) 579-1700  
Fax: (216) 579-6073

Date: Feb. 10, 2009